LIBELED: 5-16-61, Dist. P.R.

CHARGE: 503(b)(4)—when shipped, the articles were subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Disposition: 8-3-61. Default—destruction.

6789. Hy-Jet Wafers, Medcol Cotabs, and Medatinic tablets. (F.D.C. No. 45895. S. Nos. 31-330 R, 31-332/3 R.)

QUANTITY: 17,580 Hy-Jet Wafers in btls. of 12 wafers, 24 wafers, and 500 wafers; 50,000 tablets of Medcol Cotabs in bulk containers and an undetermined number of 100-tablet btls. of Medcol Cotabs; and approximately 20,000 tablets of Medatinic tablets in 100-tablet btls., at New Orleans, La., in possession of Medco Co., Inc.

SHIPPED: The *Hy-Jet Wafers* were shipped on 2-12-60, from Gardena, Calif., by S. O. Barnes & Son, Inc.; and the other articles were shipped by a different firm, from Memphis, Tenn., on 12-11-59 and 12-28-59.

Label in Part: (Btl.) "A New Concept in Feminine Hygiene Hy-Jet Wafers

* * * buffered to maintain an acid condition in the vaginal mucosa * * *

Medco Company, Inc., New Orleans, Louisiana"; "100 Cotabs MEDCOL * * *

Each Cotab contains: Pyrilamine Maleate 4 mg., Metapyrilene HCl 4 mg.

* * * Caution:"; and "100 Tablets Medatinic 500 Mg. Each Tablet Contains: Nicotinic Acid 500 Mg. (Niacin) * * * Mfg. for Medco Co., Inc., New Orleans, La."

RESULTS OF INVESTIGATION: Analysis of the *Hy-Jet Wafers* showed that they contained boric acid and phenylmercuric borate in an effervescent base. The other articles were assumed to contain the ingredients listed on their labels. The *Medcol Cotabs* and the *Medatinic tablets* contained in the bottles had been repacked by the dealer from bulk containers shipped as described above.

LIBELED: 5-24-61, E. Dist. La.

CHARGE: 502(a)—when shipped, the label of the Hy-Jet Wafers contained false and misleading representations that the article was adequate and effective for the treatment of monilia, trichomonas, staphylococcus, and streptococcus infections of the vaginal tract; and 503(b) (4)—while held for sale, the label of the Medcol Cotabs bore the statement "Caution: Federal law prohibits dispensing without prescription," and the article was not subject to 503(b) (1); and 503(b) (4)—while held for sale, the Medatinic tablets were a drug subject to 503(b) (1) and their label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: Medcol Cotabs and Medatinic tablets, 6-29-61. Consent—claimed by Medco Co., Inc., and released under bond for relabeling. Hy-Jet Wafers, 7-14-61. Default—destruction.

6790. Vigosan tablets. (F.D.C. No. 45898. S. Nos. 32-272/3 R, 32-283/4 R.)

QUANTITY: 323 25-tablet btls. and 78 50-tablet btls. at San Juan, P.R.

SHIPPED: 3-10-61 and 4-25-61, from New York, N.Y., by Gold Leaf Pharmacal Co., Inc.

Label in Part: "Vigosan * * * Gold Leaf Pharmacal Co., Inc., New Rochelle, N.Y. * * * Each tablet contains: Testosterone 2 mgm. Yohimbine HCl. 5 mgm. Vitamin E 10 mgm. Extract Damiana 60 mgm. Extract Nux Vomica 5 mgm. Dosage: One or two tablets 3 times daily."